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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/560,441 | Applicant(s) FARRELL, CHRISTOPHER JOHN | |
| | Examiner VICTORIA HICKS | Art Unit 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-18,20-30,40 and 42-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-18,20-30,40 and 42-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/15/10</u> . | 6) <input checked="" type="checkbox"/> Other: <u>boiling point of water vs. pressure</u> . |

DETAILED ACTION

This action is in response to the Request for Continued Examination (RCE) filed 7/29/10. Claims 1, 6-18, 20-30, 40 and 42-51 are currently pending in the instant application. Claims 2-5, 19, 31-39 and 41 have been cancelled by Applicant.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/29/10 has been entered.

Claim Objections

1. Claim 47 is objected to because of the following informalities: a typographical error in line 2 of the claim requires that "the upper arch of the **use**" be changed to ---the upper arch of the **user**---. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 40, 46 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 40, 46 and 51 recite device being "not user conformable or mouldable in boiling water." No support has been provided for this claim limitation in the specification. Page 13, lines 31-32 of the specification provides support that "the softening point of the resin is above 100 degrees Celsius." The boiling point of water can be above 100 degrees Celsius at higher pressures and therefore, the material is able to be conformable or mouldable in boiling water. For clarification, a reference describing the relationship between the boiling point of water and pressure has been attached.

3. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites the limitation "the body thereof" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "the open channels" in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites the limitations "the at least one or more channels" in lines 2-3 of the claim, "the interior space" in line 3 of the claim and "the channels" in line 4 of the claim. There is insufficient antecedent basis for these limitations in the claim.

6. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 recites the limitation "the base member" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 recites "a moldable teeth engaging element for co-operation with **a base member according to claim 40.**" This recitation is indefinite, as it fails to specifically point out the meets and bounds of the claim. In order to do so, Applicant must recite the specific structure of the base member of claim 40.

8. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites "an oral appliance, **as described in claim 1.**" This recitation is indefinite, as it fails to specifically point out the meets and bounds of the claim. In order to do so, Applicant must recite the specific structure of the oral appliance of claim 1.

9. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 46 recites the limitations "the outer labial flange" and "the front anterior region" in line 13 of the claim. There is insufficient antecedent basis for these limitations in the claim.

10. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 recites the limitation "the flange or skirt" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 49 recites the limitation "the front opening" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. Claim 50 recites the limitation "said side and front openings" in lines 1-2 of the claim and "the upper channel" in line 3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 6-9, 20, 40, 46, 47 and 50 are rejected under 35

U.S.C. 102(b) as being anticipated by Feldbau (US 4,350,154).

In regards to claim 1, Feldbau teaches in Figure 2 and column 2, lines 17-20, 25-32 and 51-56 a substantially rigid plastic base member (12, 14, 16) that is not user conformable or mouldable in boiling water (it is made of a molded plastic, which may not be user conformable or mouldable in boiling water), the base member (12, 14, 16) having a generally U-shaped form corresponding to the outline of a jaw of a user, at least one channel defined by a substantially rigid inner flange (16), a substantially rigid outer flange (14) and a web (12) connecting the flanges (14, 16) within which an upper or lower row of teeth of a user can be received, the substantially rigid inner flange (16), the substantially rigid outer flange (14) and the web (12) being of a rigid plastic material that is not

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user conformable or mouldable in boiling water; and a teeth engaging element (22), encapsulating each channel, being made of a material able to be user conformed or user moulded to suit the individual mouth of the user wherein the base member has a greater rigidity than the teeth engaging element, the base member (12, 14, 16) further including one or more compressible shock absorption channels (23) defined in or near terminal ends of the base member (12, 14, 16), and which extend through a posterior outer face to a posterior inner face of the base member (12, 14, 16) to substantially absorb impact shock.

In regards to claim 6, Feldbau teaches the apparatus of claim 1. Feldbau teaches in Figures 1 and 2 that the compressible shock absorption channels (23) comprise open air channels defined in the base member (12, 14, 16).

In regards to claim 7, Feldbau teaches the apparatus of claim 1. Feldbau teaches in Figures 1 and 2 that the compressible shock absorption channels (23) extend from an opening in an outer labial face of the base member (12, 14, 16), through the body thereof to an opening in an inner lingual have of the base member (12, 14, 16).

In regards to claim 8, Feldbau teaches the apparatus of claims 1 and 7. Feldbau teaches in Figures 1 and 2 that the compressible shock absorption channels (23) comprise side open channels in or near terminal ends of the generally U shaped form of the base member (12, 14, 16).

In regards to claim 9, Feldbau teaches the apparatus of claims 1, 7 and 8. Feldbau teaches in Figures 1 and 2 at least one frontal open channel (23) arranged in a front section of the base member (12, 14, 16).

In regards to claim 20, Feldbau teaches the apparatus of claim 1. Feldbau teaches in column 2, lines 51-56 that the rigid plastics material can comprise a non-thermoplastic material (but must be a molded plastic) either alone or in combination with another plastics material.

In regards to claim 40, Feldbau teaches in Figure 2 and column 2, lines 17-20, 25-32 and 51-56 an oral appliance for placing in a mouth of a user, the base member (12, 14, 16) being of a rigid plastics material that is not user conformable or mouldable in boiling water (it is made of a molded plastic, which

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may not be user conformable or mouldable in boiling water), the base member (12, 14, 16) having a generally U- shaped form corresponding to the outline of a jaw of a user, the base member (12, 14, 16) comprising at least one channel defined by a substantially rigid inner flange (16), a substantially rigid outer flange (14) and a web (12) connecting the flanges (14, 16), within which an upper or lower row of teeth of a user can be received, the substantially rigid inner flange (16), the substantially rigid outer flange (14) and the web (12) being of a rigid plastic material that is not user conformable or mouldable in boiling water, the base member (12, 14, 16) further comprising shock absorption means (23) taking the form of pre-designated compressible sections in order to substantially absorb shock.

In regards to claim 46, Feldbau teaches in Figures 1 and 2 and column 2, lines 17-20, 25-32 and 51-56 a substantially rigid plastic base member (12, 14, 16) that is not user conformable or mouldable in boiling water (it is made of a molded plastic, which may not be user conformable or mouldable in boiling water), the base member (12, 14, 16) having a generally U-shaped form corresponding to the arch of a jaw of a user having a front region extending back via two arms to a rear end, and at least one channel (in which material 22 is held) defined by a substantially rigid inner flange (16), a substantially rigid outer flange (14) and a web (12) connecting the flanges (14, 16) within which at least one upper or lower row of teeth of a user can be received, the substantially rigid inner flange (16), the substantially rigid outer flange (14) and the web (12) being of a rigid plastic material that is not user conformable or mouldable in boiling water, a

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teeth engaging element (22) received in each said channel that is made of a material that is able to be user moulded to fit the mouth of a user, the base member (12, 14, 16) including a shock absorber (23) for absorbing energy from an impact to the guard, the shock absorber (23) comprising at least one compressible side opening defined in the outer labial flange of the front anterior region such that the compressible openings absorb impact shock.

In regards to claim 47, Feldbau teaches the apparatus of claim 46. Feldbau teaches in Figures 1 and 2 that the guard defined only an upper said channel to fit over the upper arch of the user.

In regards to claim 50, Feldbau teaches the apparatus of claim 46. Feldbau teaches in Figures 1 and 2 that each of said side and front openings (23) is elongate with the longitudinal axis of the opening (23) being substantially parallel to the upper channel (in which material 22 is contained).

14. Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Orrico (US 6,170,485).

In regards to claims 44 and 45, Orrico teaches in Figure 7 and columns 3-4, lines 60-11 a substantially rigid plastic base member (26) that is not user conformable or mouldable in boiling water, the base member (26) having a generally U-shaped form corresponding to the outline of a jaw of a user, at least one channel defined by a substantially rigid inner flange, a substantially rigid outer flange and a web connecting the flanges within which an upper or lower row of teeth of a user can be received, the substantially rigid inner flange, the

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substantially rigid outer flange and the web being of a rigid plastic material that is not user conformable or mouldable in boiling water; and a teeth engaging element (28), encapsulating each channel, being made of a material able to be user conformed or user moulded to suit the individual mouth of the user wherein the base member (26) has a greater rigidity than the teeth engaging element (28), the base member (26) further including one or more compressible shock absorption channels (38) defined in or near terminal ends of the base member (26), and which extend through a posterior outer face to a posterior inner face of the base member (26) to substantially absorb impact shock; and immersing the oral appliance (10) in water having a temperature sufficiently high to make the teeth engaging element (28) moldable, inserting the appliance into a user's mouth; biting into the teeth engaging element to mould the teeth engaging element to the form of the user's jaw, and thereafter allowing the teeth engaging element to harden (set); inserting the appliance (10) into a user's mouth before partaking of any activity whereby use of a mouthguard is desirable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 10-18, 42 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldbau (US 4,350,154).

In regards to claim 10, Feldbau teaches the apparatus of claims 1, 7 and 8. Feldbau discloses the claimed invention except that the side open channels have a height in the range of 0.5-10mm and length lying in the range of 0.5-30mm. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the side open channels having a height in the range of 0.5-10mm and length lying in the range of 0.5-30mm, since it has been held that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F .2d 459, 105 USPQ 237 (CCPA 1955).

In regards to claim 11, Feldbau teaches the apparatus of claims 1, 7, 8 and 10. Feldbau discloses the claimed invention except that the side open channels that are positioned proximate to the terminal ends of the generally U shaped form of the base member have a length lying in the range 10-20mm. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the side open channels that are positioned proximate to the terminal ends of the generally U shaped form of the base member having a length lying in the range 10-20mm, since it has been held that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F .2d 459, 105 USPQ 237 (CCPA 1955).

In regards to claim 12, Feldbau teaches the apparatus of claims 1 and 7-9. Feldbau discloses the claimed invention except that the frontal open channel of the base member has a length lying in the range 2-10mm. It would have been

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obvious to one having ordinary skill in the art at the time of invention to provide the frontal open channel of the base member having a length lying in the range 2-10mm, since it has been held that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F .2d 459, 105 USPQ 237 (CCPA 1955).

In regards to claim 13, Feldbau teaches the apparatus of claim 1. Feldbau teaches in Figure 2 and column 2, lines 36-45 that the teeth engaging element (22) is made of a continuous layer of material that encapsulated the base member (12, 14, 16) to firmly and securely mount the layer of material on the base member (12, 14, 16). Feldbau does not teach that the material is thermoplastic. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the material being thermoplastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regards to claim 14, Feldbau substantially teaches the apparatus of claims 1 and 13. Feldbau teaches in Figure 2 that the continuous layer of material substantially covers the complete surface area of the base member (12, 14, 16). Feldbau does not teach that the material is thermoplastic. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the material being thermoplastic, since it has been held to be within the general skill of a worker in the art to select a known material on the

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basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416.

In regards to claim 15, Feldbau substantially teaches the apparatus of claims 1 and 13. Feldbau teaches in Figure 2 that the layer of material defines one or more openings which correspond with at least one or more of the open channels (23) arranged in the base member (12, 14, 16). Feldbau does not teach that the material is thermoplastic. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the material being thermoplastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regards to claim 16, Feldbau substantially teaches the apparatus of claims 1 and 13. Feldbau teaches in Figure 2 that the layer of material (22) extends across and covers the one or more openings (23) which correspond with the at least one or more channels (in which material 22 is contained) arranged in the base member (12, 14, 16) and closes off the interior space defined by the channels. Feldbau does not teach that the material is thermoplastic. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the material being thermoplastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regards to claim 17, Feldbau substantially teaches the apparatus of claims 1 and 13. Feldbau does not teach that the material is thermoplastic EVA (ethylvinylacetate) which softens at a temperature of 90°C-95°C. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the material being thermoplastic EVA (ethylvinylacetate) which softens at a temperature of 90°C-95°C, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regards to claim 18, Feldbau substantially teaches the apparatus of claims 1 and 13. Feldbau does not teach that the material has a thickness of 1mm-3mm. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the material thickness being 1mm-3mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 42, Feldbau teaches the apparatus of claim 40. Feldbau teaches in column 1, lines 45-48 and column 2, lines 51-56 the base member (channel member) being at least semi-flexible. Feldbau does not explicitly teach that base member being non-thermoplastic. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the base member being non-thermoplastic, since it has been held to be within the general skill of a worker in the art to select a known material on the

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basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416.

In regards to claim 51, Feldbau teaches in Figure 2 and column 2, lines 17-20, 25-32 and 51-56 a substantially rigid plastic base member (12, 14, 16) that is not user conformable or mouldable in boiling water (it is made of a molded plastic, which may not be user conformable or mouldable in boiling water), the base member (12, 14, 16) having a generally U-shaped form corresponding to the outline of a jaw of a user, and at least one channel defined by a substantially rigid inner flange (16), a substantially rigid outer flange (14) and a web (12) connecting the flanges (14, 16), within which at least one upper or lower row of teeth of a user can be received, the substantially rigid inner flange (16), the substantially rigid outer flange (14) and the web (12) being of a rigid plastic material that is not user conformable or mouldable in boiling water, and a teeth engaging element (12) encapsulating each channel, being made of a material able to be user conformed or user moulded to suit the individual mouth of the user wherein the base member (12, 14, 16) has a greater rigidity than the teeth engaging element. Feldbau does not teach that the rigid plastics material is polyethylene with less than 10% by weight of a thermoplastics material. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the rigid plastics material being polyethylene with less than 10% by weight of a thermoplastics material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of

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its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

16. Claims 21-25, 28-30, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldbau (US 4,350,154) in view of Kittelsen et al. (US 6,691,710).

In regards to claim 21, Feldbau teaches the apparatus of claims 1 and 20. Feldbau does not teach that the non-thermoplastic material comprises polyethylene, polyurethane, polypropylene or santoprine. However, Kittelsen discloses an analogous device in which the non-thermoplastic material comprises polyethylene, polyurethane, polypropylene or santoprine (Col. 5, lines 1-5). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the material taught by Feldbau with that taught by Kittelsen because this element is known to exhibit a rigid character in that it holds its shape and can handle hot water, and also has excellent bonding qualities with other copolymers, as Kittelsen teaches in column 5, lines 3-6.

In regards to claims 22-24, Feldbau teaches the apparatus of claims 1 and 20. Feldbau and Kittelsen disclose the claimed invention except for the other plastics material is a thermoplastic material and the thermoplastic material is 10% or less by weight of the base member; the base member comprises 3-8% by weight of thermoplastic material that is EVA and the balance is polyethylene; the base member comprises 4- 6% by weight of thermoplastic material that is EVA and the balance is polyethylene. In view of Kittelsen (Col. 5 line 65—Col. 6

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line 54) it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize these mixture ration, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In regards to claim 25, Feldbau and Kittelsen teach the apparatus of claims 1, 20 and 21. Feldbau does not teach that the non-thermoplastic material comprises polyethylene on its own. However, Kittelsen discloses an analogous device in which the non-thermoplastic material comprises polyethylene on its own (Col. 5, lines 20-22). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the material taught by Feldbau with that taught by Kittelsen because this element is known to exhibit a rigid character in that it holds its shape and can handle hot water, and also has excellent bonding qualities with other copolymers, as Kittelsen teaches in column 5, lines 3-6.

In regards to claim 28, Feldbau teaches the apparatus of claim 1. Feldbau does not teach a locating means for correctly locating and positioning the jaws in the teeth engaging element during fitting of the oral appliance. However, Kittelsen discloses an analogous device including locating means (106) for correctly locating and positioning the jaws in the teeth engaging element during fitting of the oral appliance (Col. 4, lines 56-59). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the base taught by Feldbau with the locating means taught by Kittelsen because this

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element is known to permit proper positioning of the lower jaw, as Kittelsen teaches in column 4, lines 56-59.

In regards to claim 29, Feldbau and Kittelsen teach the apparatus of claims 1 and 28. Feldbau does not teach a locating means. However, Kittelsen discloses in Figure 5 and column 4, lines 56-59 an analogous device in which the locating means (106) comprises a brace arranged externally on the teeth engaging element (70). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the base taught by Feldbau with the locating means taught by Kittelsen because this element is known to permit proper positioning of the lower jaw, as Kittelsen teaches in column 4, lines 56-59.

In regards to claim 30, Feldbau and Kittelsen teach the apparatus of claims 1 and 28. Feldbau and Kittelsen disclose the claimed invention except that the brace comprises rubber. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the brace comprising rubber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regards to claim 43, Feldbau teaches in Figure 2 and column 2, lines 17-20, 25-32 and 51-56 an oral appliance for placing in a mouth of a user, the base member (12, 14, 16) being of a rigid plastics material that is not user conformable or mouldable in boiling water (it is made of a molded plastic, which may not be user conformable or mouldable in boiling water), the base member (12, 14, 16) having a generally U- shaped form corresponding to the outline of a

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jaw of a user, the base member (12, 14, 16) comprising at least one channel defined by a substantially rigid inner flange (16), a substantially rigid outer flange (14) and a web (12) connecting the flanges (14, 16), within which an upper or lower row of teeth of a user can be received, the substantially rigid inner flange (16), the substantially rigid outer flange (14) and the web (12) being of a rigid plastic material that is not user conformable or mouldable in boiling water, the base member (12, 14, 16) further comprising shock absorption means (23) taking the form of pre-designated compressible sections in order to substantially absorb shock; and a moldable teeth engaging element (22) for co-operation with the base member (12, 14, 16), the element (22) being made of a material able to be user conformed or user molded to suit the individual mouth of the user. Feldbau does not teach a locating means. However, Kittelsen discloses an analogous device including locating means (106) for correctly locating and positioning the jaws in the teeth engaging element during fitting of the oral appliance (Col. 4, lines 56-59). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the base taught by Feldbau with the locating means taught by Kittelsen because this element is known to permit proper positioning of the lower jaw, as Kittelsen teaches in column 4, lines 56-59.

17. Claims 26, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldbau (US 4,350,154) in view of Adell (US 4,955,393).

In regards to claim 26, Feldbau teaches the apparatus of claim 1. Feldbau does not teach that the base member has inner and outer flanges interconnected by a web which collectively define upper and lower channels within which the upper and lower rows of teeth of the user are receivable, wherein an upper teeth engaging element is receivable in the upper channel and a lower teeth engaging element is receivable in the lower channel. However, Adell teaches in Figures 1, 2 and 4 and column 3, lines 5-10 that the base member (20) has inner (30) and outer (32) flanges interconnected by a web (44) which collectively define upper and lower channels within which the upper and lower rows of teeth of the user are receivable, wherein an upper teeth engaging element (24) is receivable in the upper channel and a lower teeth engaging element (26) is receivable in the lower channel. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the base member taught by Feldbau with the inner and outer flanges interconnected by a web (44) which collectively define upper and lower channels taught by Adell because this element is known to enable to device of Feldbau to correspond to both the upper and lower dental arches of the user, as Adell teaches in column 3, lines 5-8.

In regards to claim 48, Feldbau teaches the apparatus of claims 46 and 47. Feldbau does not teach that the outer flange includes a downward extension that extends down from the web in a direction away from the upper channel and the side openings are defined in the outer flange in the flange or skirt below the web. However, Adell teaches in Figures 1, 2 and 4 an analogous device in which the outer flange (30) includes a downward extension that extends down from the

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web (44) in a direction away from the upper channel and the side openings (38) are defined in the outer flange (30) in the flange or skirt below the web (44). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the outer flange taught by Feldbau with that downward extension taught by Adell because this element is known to enable to device of Feldbau to correspond to both the upper and lower dental arches of the user, as Adell teaches in column 3, lines 5-8.

In regards to claim 49, Feldbau and Adell teach the apparatus of claims 46-48. Feldbau does not teach the outer flange extending below the web. However, Adell teaches in Figures 1, 2 and 4 that the front opening (38) is also defined in the outer flange (30) below the web (44). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the outer flange taught by Feldbau with the outer flange extending below the web taught by Adell because this element is known to enable to device of Feldbau to correspond to both the upper and lower dental arches of the user, as Adell teaches in column 3, lines 5-8.

18. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldbau (US 4,350,154), in view of Kittelsen et al. (US 6,691,710) and further in view of Hays et al. (US 5,092,346).

In regards to claim 27, Feldbau teaches the apparatus of claim 1. Feldbau does not teach a tongue tag on the inner flange of the base member, the tongue tag being substantially centrally positioned for correctly positioning the tongue of

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a user during use, and a cut-out defined in the outer flange of the base member for allowing the appliance to adapt to varying arch sizes, and breathing apertures defined in the base member for facilitating breathing by a user when wearing the appliance. However, Kittelsen et al. teaches in Figures 7 and 8 and column 6, lines 18-22 an analogous device with a cut-out (124) defined in the outer flange (122) of the base member (70) for allowing the appliance to adapt to varying arch sizes. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the outer flange taught by Feldbau with the cut-out taught by Kittelsen et al. because this element is known to enable the base member to be customizable, as Kittelsen et al. teaches in column 6, lines 18-22. Feldbau and Kittelsen et al. do not teach a tongue tag on the inner flange of the base member, the tongue tag being substantially centrally positioned for correctly positioning the tongue of a user during use, and breathing apertures defined in the base member for facilitating breathing by a user when wearing the appliance. However, Hays et al. teaches in Figures 1 and 2, the abstract and column 5, lines 3-13 an analogous device with a tongue tag (ramp 14) on the inner flange 912, 14, 16, 18) of the base member (10), the tongue tag (ramp 140 being substantially centrally positioned for correctly positioning the tongue of a user during use, and a breathing aperture (20) defined in the base member (10) for facilitating breathing by a user when wearing the appliance. Hays et al. does not disclose multiple breathing apertures. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide multiple breathing apertures, since it has been held that mere duplication of the essential

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working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the inner flange taught by Feldbau as modified by Kittelsen et al. with the tongue tag and breathing aperture taught by Hays et al. because these elements are known to induce the lower jaw and tongue to a more forward position, resulting in a significant reduction in snoring, as Hays et al. teaches in the abstract.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA HICKS whose telephone number is (571)270-7033. The examiner can normally be reached on Monday through Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. H./
Examiner, Art Unit 3772
11/30/10

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772